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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/228,855	01/12/99	MCALEER J	SELFP016US

021121
OPPEDAHL AND LARSON LLP
P O BOX 5270
FRISCO CO 80443-5270

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EXAMINER	
NOGUEROLA, A	
ART UNIT	PAPER NUMBER
1743	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

Office Action Summary	Application No. 09/228,855	Applicant(s) McAleer et al.
	Examiner Alex Noguerola	Group Art Unit 1743

☒ Responsive to communication(s) filed on *Jan 12, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-34* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-34* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Oath/Declaration

1. Applicant notes in the specification (page 1) that the application is a CIP; however, this is not indicated in the declaration.

Information Disclosure Statement

2. Applicant is requested to provide copies of the following references which are cited on applicant's IDS of July 23, 1999, but have not been found

a.) abstract of JP 5512406

b.) JP 5510583

c.) JP 5510584

d.) JP 5510581

e.) EP 170375

f.) WO 9702847.

Claim Objections

3. Claim 1 is objected to because of the following informalities:

a) claim 1, line 14: should "species" be -- element -- ?

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 4-6, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. (WO 94/27140) in view of Nankai et al. (US 5,185,256).

Addressing claim 1. Black et al. teach a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising

(a) a substrate;

(b) a first conductive element disposed on the substrate;

(c) a second conductive element disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip;

(d) a non-conductive blood separation layer disposed over the first conductive element, said blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive element;

(e) contacts for making an electrical connection between the first and second conductive elements and the test meter.

See the abstract and Figures 1 and 2.

Black et al. do not teach reagents for the electrochemical detection of the analyte disposed in the separation layer; in Black et al. these reagents are incorporated into the electrode (next to last paragraph on page 10). Nankai et al. teach a reagent test strip having an integrated reagent/blood separation layer disposed over a first conductive element (the abstract; Fig. 3; and col. 3, ll. 50-55). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have the reagents for the electrochemical detection of the analyte disposed in the separation layer as taught by Nankai et al. in the invention of Black et al. because as disclosed by Nankai et al. the electrodes can be heat treated to provide more stable performance (Figs. 6 and 7 and col. 4,

ll. 23-56). If the electrodes are heated with the reagents there is possibility of inactivating or damaging the reagents.

Addressing claims 2, 5, 13, and 16. See in Black et al. the first paragraph on page 16.

Addressing claims 4 and 19. See in Black et al. the third paragraph from the bottom on page 9.

Addressing claims 6, 17, and 21. Black uses dimethylferocene ethanolamine as a redox mediator (pg. 10, next to last paragraph and pg. 16, top). Using ferricyanide as a redox mediator is also known in the art. See, for example, in Nankai et al. col. 3, ll. 59-64. Barring evidence to the contrary it would have been obvious to one with ordinary skill in the art how to select among known mediators one that is appropriate for the particular reaction system, particularly on the basis of the enzymes involved, and the desired results. For example, Black uses dimethylferocene ethanolamine in combination with cholesterol oxidase. Nakai et al. use ferricyanide in combination with glucose.

Additionally, Nakai et al. teach that stability and speed of response are factors to consider. Ferricyanide offers more stability with respect to p-benzoquinone, but p-benzoquinone offers a much faster response. See col. 6, ll. 27-35.

Addressing claim 11. See in Nankai et al. element 16 in Fig. 3.

Addressing claim 12. See in Nankai et al. Fig. 3.

6. Claims 3, 7, 8-10, and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. (WO 94/27140) in view of Nankai et al. (US 5,185,256) as applied to claims 1, 2, 4-13, 15-21 above, and further in view of Jones (EP 207370 A2).

Addressing claims 3 and 14. Black et al. in view of Nankai et al. do not mention that the matrix comprises silica having hydrophobic and hydrophillic surfaces, although Black et al. do disclose having hydrophobic and hydrophillic surfaces (page 11, bottom - page 12 bottom). Jones teaches a reagent test strip having a matrix comprising silica having hydrophobic and hydrophillic surfaces. See the abstract; claim 8; and page 31, line 33 - page 32, line 33. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use silica having hydrophobic and hydrophillic surfaces as taught by Jones in Black et al. in view of Nankai et al. because as taught by Jones the efficiency, accuracy, and linear response of the sensor will all be improved (page 13, ll. 14-32).

Addressing claims 7 and 18. Jones et al. do not mention the particular weight ranges claimed. However, Jones et al. do teach in detail various possible compositions that will vary elasticity and tensile strength of and provide additional properties to the separation layer (page 15, line 28 -

page 36, line 9). Barring evidence to the contrary such as unexpected results the weight percents of silica and binder will be determined by factors such as desired elasticity, tensile strength, and the presence of additives such as thickeners or antifoaming agents. As for the weight percents of redox mediator and amount of enzyme, the relative amounts of each will be determined to a large extent by the range of expected amount of analyte.

Addressing claim 8. See in Black et al. the third paragraph from the bottom on page 9.

Addressing claim 9. See in Black et al. the first paragraph on page 16.

Addressing claim 10. Black uses dimethylferocene ethanolamine as a redox mediator (pg. 10, next to last paragraph and pg. 16, top). Using ferricyanide as a redox mediator is also known in the art. See, for example, in Nankai et al. col. 3, ll. 59-64. Barring evidence to the contrary it would have been obvious to one with ordinary skill in the art how to select among known mediators one that is appropriate for the particular reaction system, particularly on the basis of the enzymes involved, and the desired results. For example, Black uses dimethylferocene ethanolamine in combination with cholesterol oxidase. Nakai et al. use ferricyanide in combination with glucose. Additionally, Nakai et al. teach that stability and speed of response are factors to consider. Ferricyanide offers more

stability with respect to p-benzoquinone, but p-benzoquinone offers a much faster response. See col. 6, ll. 27-35.

Addressing claim 15. See in Black et al. the third paragraph from the bottom on page 9.

Addressing claim 16. See in Black et al. the first paragraph on page 16.

Addressing claim 17. Black uses dimethylferocene ethanolamine as a redox mediator (pg. 10, next to last paragraph and pg. 16, top). Using ferricyanide as a redox mediator is also known in the art. See, for example, in Nankai et al. col. 3, ll. 59-64. Barring evidence to the contrary it would have been obvious to one with ordinary skill in the art how to select among known mediators one that is appropriate for the particular reaction system, particularly on the basis of the enzymes involved, and the desired results. For example, Black uses dimethylferocene ethanolamine in combination with cholesterol oxidase. Nakai et al. use ferricyanide in combination with glucose. Additionally, Nakai et al. teach that stability and speed of response are factors to consider. Ferricyanide offers more stability with respect to p-benzoquinone, but p-benzoquinone offers a much faster response. See col. 6, ll. 27-35.

Addressing claim 19. See in Black et al. the third paragraph from the bottom on page 9.

Addressing claim 20. See in Black et al. the first paragraph on page 16.

Addressing claim 21. Black uses dimethylferocene ethanolamine as a redox mediator (pg. 10, next to last paragraph and pg. 16, top). Using ferricyanide as a redox mediator is also known in the art. See, for example, in Nankai et al. col. 3, ll. 59-64. Barring evidence to the contrary it would have been obvious to one with ordinary skill in the art how to select among known mediators one that is appropriate for the particular reaction system, particularly on the basis of the enzymes involved, and the desired results. For example, Black uses dimethylferocene ethanolamine in combination with cholesterol oxidase. Nakai et al. use ferricyanide in combination with glucose. Additionally, Nakai et al. teach that stability and speed of response are factors to consider. Ferricyanide offers more stability with respect to p-benzoquinone, but p-benzoquinone offers a much faster response. See col. 6, ll. 27-35.

7. Claims 1 and 22-24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maley et al. (US 5,601,694) in view of Jones (EP 207370 A2).

Addressing claim 1. Maley et al. teach a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising

(a) a substrate;

(b) a first conductive element disposed on the substrate;

(c) a second conductive element disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip;

(d) a non-conductive reagent layer disposed over the first conductive element, said reagent layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix;

(e) contacts for making an electrical connection between the first and second conductive elements and the test meter.

Maley et al. do not specifically mention that the matrix is effective to exclude blood cells; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made that the matrix is effective to exclude blood cells because the disclosure strongly suggests so in several respects:

- "[t]he membrane materials described herein are *very compatible with whole blood* **98**, have a durable surface and are *highly selective to oxygen* penetration so that a sufficient stoichiometric

excess of oxygen permeates the membrane **94** even from whole blood [emphasis added]" (col. 22, ll. 43-48); and

- Maley et al. incorporates by reference Jones et al., EP 207370 B1 (col. 17, ll. 46-63) for further details on the separation layer (note that the examiner only has a copy of EP 207370 A2, but there should be no difference with respect to the disclosure. A B1 document is one that has been examined, but not amended (this is a B2). An A2 is one that has a search report). Jones et al. teach that the "membrane is used to separate high molecular weight blood components, e.g. proteins and cellular components of the blood, from the glucose. This membrane must be permeable to glucose but relatively impermeable to the larger molecular and cellular components of blood" (pg. 6, ln. 33 - pg. 7, ln. 3). Also, "[w]hole blood is applied directly onto the membrane, allowing passage of glucose and oxygen to the glucose oxidase layer while preventing passage of substantially all other electrode interferants present in whole blood" (the abstract).

Addressing claim 22. Maley et al. teach a method for forming a disposable test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising

(a) forming first and second conductive elements on a substrate;

(b) forming a layer of insulation covering the first conductive element, said layer of insulation having a first aperture therein aligned with a portion of the first conductive element in a sample in a sample application region; and

(c) forming a reagent layer disposed on the insulation layer and making contact with the first conductive element through the first aperture in the insulation layer comprising reagents for the electrochemical detection of glucose dispersed in a non-conductive matrix, whereby the first conductive element is isolated from direct contact with a sample placed on the test strip.

See the abstract; Fig. 9A, 9B, and 25; and col. 24, ln. 10 - col. 26, ln. 56.

Maley et al. do not specifically mention that the matrix is effective to exclude blood cells; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made that the matrix is effective to exclude blood cells because the disclosure strongly suggests so in several respects:

- "[t]he membrane materials described herein are *very compatible with whole blood* **98**, have a durable surface and are *highly selective to oxygen* penetration so that a sufficient stoichiometric excess of oxygen permeates the membrane **94** even from whole blood [emphasis added]" (col. 22, ll. 43-48); and

- Maley et al. incorporates by reference Jones et al., EP 207370 B1 (col. 17, ll. 46-63) for further details on the separation layer (note that the examiner only has a copy of EP 207370 A2, but there should be no difference with respect to the disclosure. A B1 document is one that has been examined, but not amended (this is a B2). An A2 is one that has a search report). Jones et al. teach

that the "membrane is used to separate high molecular weight blood components, e.g. proteins and cellular components of the blood, from the glucose. This membrane must be permeable to glucose but relatively impermeable to the larger molecular and cellular components of blood" (pg. 6, ln. 33 - pg. 7, ln. 3). Also, "[w]hole blood is applied directly onto the membrane, allowing passage of glucose and oxygen to the glucose oxidase layer while preventing passage of substantially all other electrode interferants present in whole blood" (the abstract).

Addressing claims 23 and 24. See Fig. 25 in Maley et al.

8. Claims 2-21 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maley et al. (US 5,601,694) in view of Jones (EP 207370 A2) as applied to claims 1, 22-24 above, and further in view of Nankai et al. (US 5,185,256).

Addressing claims 2, 13, and 25. Maley et al. do not appear to mention a redox mediator. Nankai et al. teach a reagent test strip having an integrated reagent/blood separation layer disposed over a first conductive element (the abstract; Fig. 3; and col. 3, ll. 50-55), wherein the reagent layer includes redox mediator (col. 3, ll. 60-64). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a redox mediator as taught by Nankai et al. in the

invention of Maley et al. because as taught by Nankai et al. the redox mediator will stabilize the reaction (col. 6, ll. 27-30).

Addressing claims 3, 14, and 26. See in Maley et al. col. 19, ll. 7-19.

Addressing claims 4, 8, 15, 19, 27 and 31. Maley et al. do not mention that the conductive elements comprise carbon. Nankai et al. teach a reagent test strip having an integrated reagent/blood separation layer disposed over a first conductive element (the abstract; Fig. 3; and col. 3, ll. 50-55), wherein the conductive elements are mostly carbon (the abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use carbon as taught by Nankai et al. in the invention of Maley et al. because carbon is much less expensive than platinum or gold, e.g.

Addressing claims 5, 9, 16, 20, 28 and 32. See Fig. 25 in Maley et al.

Addressing claims 6, 10, 17, 29 and 33. Black uses dimethylferocene ethanolamine as a redox mediator (pg. 10, next to last paragraph and pg. 16, top). Using ferricyanide as a redox mediator is also known in the art. See, for example, in Nankai et al. col. 3, ll. 59-64. Barring evidence to the contrary it would have been obvious to one with ordinary skill in the art how to select

among known mediators one that is appropriate for the particular reaction system, particularly on the basis of the enzymes involved, and the desired results. For example, Black uses dimethylferocene ethanolamine in combination with cholesterol oxidase. Nakai et al. use ferricyanide in combination with glucose. Additionally, Nakai et al. teach that stability and speed of response are factors to consider. Ferricyanide offers more stability with respect to p-benzoquinone, but p-benzoquinone offers a much faster response. See col. 6, ll. 27-35.

Addressing claims 7, 18, and 30. Maley et al. do not mention the particular weight ranges claimed. However, Maley et al. and Jones do teach in detail various possible compositions that will vary elasticity and tensile strength of and provide additional properties to the separation layer (in Maley et al. see col. 17, ln. 46 - col. 22, ln. 18 and in Jones page 17, line 15 - page 35, line 29). Barring evidence to the contrary such as unexpected results the weight percents of silica and binder will be determined by factors such as desired elasticity, tensile strength, and the presence of additives such as thickeners and antifoaming agents. As for the weight percent of redox mediator and amount of enzyme, the relative amounts of each will be determined to a large extent by the range of expected amount of analyte.

Addressing claims 11 and 12. See Fig. 25 in Maley et al.

Addressing claim 34. See Fig. 9B in Maley et al.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex Noguerola whose telephone number is (703)-305-5686.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703)-308-4037. The unofficial fax phone number, for example, for faxing a proposed amendment, for this Group is (703)-305-7719. The official fax phone number, for example, for faxing an amendment to be entered, for this Group is (703)-305-7718.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)-308-0651.

Alex Noguerola

April 4, 2000

Jill Warden
Supervisory Patent Examiner
Technology Center 1700